K093863

MAY 10 2010

510k Summary of Epidrum

Owner: Exmoor Plastics Limited
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Prepared on: 29th September 2009

Trade Name: Epidrum

Common Name: Loss of Resistance Device

Classification Name: Piston syringe

Class: II

Regulation Number: 880.5860

Product Code: FMF

Device Description: The Epidrum comprises a small chamber, featuring a female Luer inlet port and a male Luer exit port on opposing sides, with an expandable membrane as one of the sides between the ports.

The Epidrum is a single use device, manufactured from medical grade polymers.

Intended use: The Epidrum is intended for use in epidural procedures between a luer syringe and an epidural needle to give a clear visual signal that the needle tip has entered the epidural space.

Indications for Use:

The Epidrum is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space.

Equivalent Device: Avid-Nit Loss of Resistance Syringe

510K Number: K001731

Manufacturer: Avid Medical Inc.
9000 Westmont Drive
Stonehouse Commerce Park
Toano
Virginia 23168

Comparison:	**Epidrum**	**Avid-nit LOR Syringe**
Intended Use	Intended for use between a Luer syringe and an epidural needle to give a clear visual signal that the needle tip has entered the epidural space.	Intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space by the Loss of Resistance technique as explained in standard medical textbooks.
Indications For Use	The Epidrum is intended for use, in conjunction with an epidural needle to verify the needle tip placement in the epidural space.	The AVID-NIT Loss of Resistance Syringe is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space
Technological Differences:	The design incorporates an expandable membrane which deflates when the needle tip enters the epidural space giving an instantaneous, clear, visual signal.	The loss of resistance to the plunger of the syringe, when the distal tip of the needle penetrates the epidural space, is sensed by touch via the user's thumb.

Conclusion: Although the Epidrum uses different senses of the user (visual:touch) from the Loss of Resistance Syringe mentioned above, it operates on precisely the same loss of resistance principle, has the same intended use and raises no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Margaret Blackmore
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Lisieux Way
Taunton, Somerset
United Kingdom TA1 2LB

MAY 10 2010

Re: K093863
Trade/Device Name: EPIDRUM
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 26, 2010
Received: April 27, 2010

Dear Ms. Margaret Blackmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

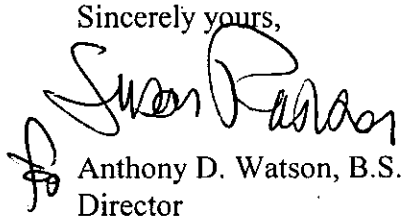
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exmoor

Indications for Use

510(k) Number (if known):

Device Name: Epidrum

Indications For Use:

The Epidrum is intended for use, in conjunction with an epidural needle, to verify the needle tip placement in the epidural space.

Prescription Use **YES**
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use **NO**
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schuette

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093863